Applicant: Rachel Meyers et al. Attorney's Docket No.: 10448-046002 / MPI2000-

185P1R2

Serial No.: 09/846,512

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# **REMARKS**

Claims 19 and 54-57, 59-63 and 65-82 are pending. Claims 19 and 63 have been amended. Claims 1-18, 20-53, 58 and 64 have been canceled. New claims 69-82 have been added. Support for the new claims can be found, e.g., at page 38, lines 16-18 of the application. No new matter has been added.

#### **Priority**

The claims, as amended, are directed to methods that include contacting the polypeptide of SEQ ID NO:2, a polypeptide having at least 95% homology to SEQ ID NO:2, or a polypeptide that differs from SEQ ID NO:2 by at least 1 but less than 5 amino acid residues. Support for such polypeptides can be found in U.S. Serial Number 09/633,300 (see, e.g., page 47, lines 23-28 and page 48, lines 7-10) and U.S. Provisional Serial Number 60/200,621 (see, e.g., page 29, lines 19-33). Therefore, the claims currently pending are entitled an earliest priority date of April 28, 2000.

## Rejection of Claims 63 and 64 Under 35 U.S.C. §112, second paragraph

Claims 63 and 64 are rejected under 35 U.S.C. §112, second paragraph "as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." In particular, the Examiner asserts that the claims are "incomplete for omitting essential steps ... the requirements for method steps minimally include a contacting step ..., a detection step ..., and a correlation step describing how the results of the assay allow for determination."

Claim 64 has been cancelled and claims 63 has been amended to include a contacting step, a detection step and a correlation between the method and the results, thereby obviating this rejection.

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### Rejection of Claims 19, 58, 63 and 64 Under 35 U.S.C. §112, first paragraph

Claims 19, 58, 63 and 64 are rejected under 35 U.S.C. §112, first paragraph "as failing to comply with the enablement requirement." In particular, the Examiner states that

Claim 19, 58, 63 and 64 are interpreted as drawn to method comprising contacting a cell expressing SEQ ID NO:12 with a compound, detecting hydrolysis of said compound, and concluding said compound either binds or interact SEQ ID NO:12 when hydrolysis of said compound is detected. Underwood et al ... or Scott et al ... teach that a cell (a live organism) has many proteases whose function, i.e., hydrolysis of peptide bond, are similar to instant SEQ ID NO:12. The specification does not teach how to determine whether hydrolysis of a compound is caused by SEQ ID NO:12 or any other proteases of a cell.

Claims 58 and 64 have been cancelled, thereby obviating this rejection with regards to claims 58 and 64. With regard to claims 19 and 63, Applicants respectfully traverse this rejection.

Claim 19 is directed to a method that includes contacting a claimed polypeptide or a cell expressing the claimed polypeptide with a test compound and determining whether the polypeptide binds to the test compound. Thus, claim 19 requires a determination of whether the claimed polypeptide binds to a test compound. The Examiner has read claim 19 as only having one way of determining binding, namely by hydrolysis of the test compound. However, several different techniques are known and can be used to determine binding. For example, competition binding assays, proximity assays, two-hybrid assays, and the detection of labeled complexes can be used to determine if binding occurs between the polypeptide and a test compound. In fact, Applicants have described many different art-known assays for determining binding. See, e.g., pages 57 to 66 of the application. To satisfy the enablement requirements, Applicants do not need to teach each and every method that can be used to evaluate binding between the claimed polypeptide and a test compound. Applicants have provided several different methods of performing the claimed method, and thus, have meet their burden. Thus, it is clear that the method of claim 19 can be performed without undue experimentation, and Applicants respectfully request that the Examiner withdraw this rejection.

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Claim 63 is directed to methods of evaluating the effect of interaction between a test compound and the claimed polypeptide. Thus, contrary to the Examiner's assertions, the claimed method does not recite testing any test compound to determine hydrolysis. Instead, the claim recites evaluating a test compound that interacts with the claimed polypeptide to determine the effect of such interaction, namely does the interaction result in hydrolysis of the test compound. Since the test compound interacts with the claimed polypeptide, it is likely that hydrolysis of the test compound is caused by interaction with the claimed polypeptide, and not some other unrelated protease of the cell. As such, the method recited in claim 63 is enabled and Applicants respectfully request that the Examiner withdraw this rejection.

Claim 64 is also rejected under 35 U.S.C. §112, first paragraph, "as failing to comply with the written description requirements." Claim 64 has been cancelled, thereby obviating this rejection.

# Rejection of Claims 19, 54, 55, 56, 59 and 68 Under 35 U.S.C. §102(b)

Claims 19, 54, 55, 56, 59 and 68 are rejected under 35 U.S.C. §102(b) "as being anticipated by Underwood et al, Biochim Biophys Acta. 2000 Nov 15;1502(3):337-50."

Applicants respectfully traverse this rejection. The claims, as amended, are entitled to a priority date of April 28, 2000. Since the Underwood et al. reference has a publication date after April 28, 2000, it is not prior art against the claimed invention. Therefore, Applicants respectfully request that the Examiner withdraw this rejection.

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Enclosed is a check for the Petition for Extension of Time fee. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

Date:

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